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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,860	11/29/2001	Geert Maertens	2551-69	4135

23117 7590 10/07/2005

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EXAMINER	
LI, BAO Q	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 10/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/995,860	MAERTENS ET AL.	
	Examiner	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16,17,21-36 and 38-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *16* is/are allowed.

6)☒ Claim(s) *17,27-36 and 38-42* is/are rejected.

7)☐ Claim(s) *21-25* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 06/21/2005
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Decision of petition under 37 C.F.R 1.181

The petition under 37 C.F.R. 1. 18 1, to request review of the restriction requirement is GRANTED. Groups l through III have already been rejoined and are under examination. Group IV, claims 27-35, are directed to a method having identical active step to the method of claim 36, which is already under examination; therefore, claims 27-35 are rejoined to the currently examined claims as a result of this petition decision. Accordingly, claims 16-17, 21-36 and 38-42 are considered before the examiner.

Because the office action including the rejoined claims 27-35, a new first office action is issue accordingly.

Final Office Action mailed on October 19, 2004

In the previous Office Action, Applicants argue that previous Office Action mailed on October 29, 2004 is premature since the rejection included a new rejoined claim 17. The argument has been fully considered. The rejection of claim 17 is not based on any new reference and any new opinion different from the outstanding rejection. The Office action made Final was reviewed and signed by the primary examiner James Housel.

Response to Amendment

This is a response to the amendment filed 08/12/05. Claims 16-17, 2125, 26 38, 39 have been amended. The status of all claims are summarized as following:

Claims 1-15, 18, 19, 20, 37 and 43 have been canceled.

Claims 16-17, 21-36 and 38-42 are pending before the examiner.

Objection

The amendment filed on 08/12 2005 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. In the instant case, the

amendment of specification on page 85 about peptide IGP 1626 of SEQ ID NO: 112 is different from the sequence of SEQ ID NO: 112 as it was originally filed because it has missed the 1st amino acid residue of Y. Therefore, it has not been entered. Applicant is required to cancel the new matter in the reply to this Office Action or revise the amendment in the next response.

Please note any ground of rejection(s) that has not been repeated is removed. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Double Patenting Rejection

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

2. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

3. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. An obviousness-type double-patenting rejection is appropriate where the conflict claims are not identical but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim(s) is either anticipated by or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 14U F.3d 1428, 46

USPQZd 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQZd 2010 (Fed. either anticipated by, 1993); In re Longi, F.2d 887, 225 US/Q 645 (Fed. Cir. 1985).

5. Claims 17 and 26 is still rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 16 of U.S. Patent No. 6, 635,257 B1 on the same ground as stated in the previous Office Action.

6. While applicants amend claims to the E1 protein as a protein consisting of amino acid residues 192-326 of the HCV polyprotein, it is the same E1s protein that is claimed in the claim 16 of issued patent "257B1". Moreover, in the response, applicants did not object the rejection and stated that they will consider to fill a terminal disclaimer if an allowable subject matter is identified upon allowance. The rejection is, therefore, maintained.

7. Claims 27-29, 31-36, 38-42 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 40 and 47 of copending application No. 09/995, 791 on the same ground as stated in the previous Office Action.

8. While applicants amend claims to the E1 protein as a protein consisting of amino acid residues 192-326 of the HCV polyprotein, it is the same E1s protein that is claimed in the claims 40 and 47 of co-pending application 09/995,791. Moreover, in the response, applicants did not object the rejection and stated that they will consider to fill a terminal disclaimer if an allowable subject matter is identified upon allowance. The rejection is, therefore, maintained.

9. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claims 27-29, 31-36, 38-42 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 40-41, 43, 45, 50, 53, 54, 63-65, 67-70 of copending Application No. 10, 321, 798. Although the conflicting claims are not identical, they are not patentably distinct from each other

because: both sets of claims are directed to a method of using an immunogenic composition for treating the chronic liver inflammation caused by HCV infection, wherein the composition comprises at least one HCV envelope E1 protein ranged from amino acid residues 192-326 or part thereof, and pharmaceutical accepted carrier, adjuvant or vehicle. While the reduced or improved symptoms by administration of the claimed HCV E1 consisting of amino acid residues 192-326 are claimed differently, the claimed methods comprises identical active steps of using the HCV E1 polypeptide in the same population of HCV infected patients suffering the chronic liver diseases. The outcomes of using the same identical active steps presented by different clinical parameters are not considered as active steps of claimed method of using HCV E1 polypeptide consisting of amino acids 192-326. Therefore, they are considered to be anticipated each other in term of using same active steps of the methods.

11. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claim 30 recites the limitation "HCV core and/or HCV E2 antigens" in 29 and claims 16-17. There is insufficient antecedent basis for this limitation in the claims 29, 16-17 because the claims 29, 16-17 are directed to the HCV antigen as HC E1. There is not HCV core and/or core motioned in the above claims.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 7:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BAOGUN LI, MD
PATENT EXAMINER

Baogun Li

Bao Qun Li
09/29/2005